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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,187	04/21/2000	Amy E. Baker	425802000200	7012
25226	7590	07/28/2004		
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER MITCHELL, GREGORY W	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 07/28/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/557,187

**Applicant(s)**

BAKER, AMY E.

**Examiner**

Gregory W Mitchell

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-11,13 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 7-11, 13 and 15-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

This office action is in response to Applicant's amendment and remarks filed on April 22, 2004 wherein claims 1 and 11 have been amended. Currently, claims 1, 2, 4, 5, 7-11, 13 and 15-22 are pending.

In view of Applicant's amendments and remarks submitted on April 22, 2004, Examiner's 35 U.S.C. 112(2) rejections of claims 1, 2, 4, 5, 7-11, 13 and 15-22 has been withdrawn with regard to the "likelihood" portion of the rejection. Examiner has found Applicant's arguments regarding the 35 U.S.C. 103 rejections and the 35 U.S.C. 112(2) "above about" rejections of claims 1, 2, 4, 5, 7-11, 13 and 15-22 unpersuasive and the rejections are maintained.

***Response to Arguments***

Applicant's arguments filed April 22, 2004 regarding the 35 U.S.C. 112(2) rejection of claims 1 and 11 have been fully considered but they are not persuasive. In light of Applicant's amendments to claims 1 and 11, the "likelihood" portion of the rejection has fallen, necessitating the withdrawal of that portion of the rejection. The portion of the rejection regarding the indefiniteness of the phrase "above about" is maintained. Examiner does not find Applicant's arguments that the "term 'about' has consistently been held by the courts to be clear and definite" as persuasive because Examiner is not objecting to the term "about" but to the phrase "above about." Examiner concedes that the term "about" is definite and if Applicant removed the term "above," the claim would be rendered definite. The combination of the terms "above" and "about" render the claim indefinite, however, for the reasons described in the previous office action and specifically because it is not clear what pH is within the claimed range of

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“above about” 5. The phrase could be interpreted to mean above 5, but only slightly above 5 or it could be interpreted as simply being greater than any value equal to about 5.

In response to applicant's argument that the recitation, “adapted only for administration to non-facial body skin,” is a true limitation of independent claim 1 and dependent claims 2, 4, 5, 7-11, 13 and 15-22, Examiner holds that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. *If the prior art structure is capable of performing the intended use, then it meets the claim.* In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant application, the phrase “adapted only for administration to non-facial body skin” does not provide any additional limitation to the composition or characteristic of the spray. Therefore, because it would have been obvious, for the reasons described in the office action filed December 22, 2003, to prepare the spray claimed, the recitation “adapted only for the administration to non-facial body skin” is merely an intended use and no weight is given thereto. Furthermore, Applicant's argument that weight should be given to the aforementioned recitation because “[i]t is clearly the Applicant's intention that [the] feature be encompassed by claim 1” is unpersuasive because Applicant is only claiming a “fine mist spray” composition. The intended use is not given any weight for the reasons discussed above.

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Applicant further argues that the recitation “whereby any nasal irritation or coughing caused by the fine mist spray is thereby reduced” should be considered a limitation of the claimed subject matter. Examiner maintains that this is an inherent property of a salicylic acid containing fine mist spray with a pH above 5. Applicant objects to Examiner’s characterization of this property as being inherent arguing, “examiner must provide a basis in fact and/or technical reasoning to support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the applied prior art.” As stated in the office action dated December 22, 2003, the prior art reference, Briggs et al. (US 5976521) teaches an anti-acne composition comprising salicylic acid with a pH of 1-7. Examiner provided extrinsic evidence, Boettcher et al. (US 4287190), in the previous office action that “the missing descriptive matter is necessarily present in the prior art,” see §MPEP 2112, namely that as the pH of Briggs et al. increased from 1 to 7, irritation caused by the salicylic acid would decrease. About two decades prior to Applicant’s application, Boettcher et al. disclosed that it was advantageous to increase the pH of salicylic acid to prevent irritation (column 2, lines 42-46). Accordingly, given the length of time that it has been known that an increase in pH will prevent irritation, it is Examiner’s position that the missing component (i.e. “whereby any nasal irritation or coughing caused by the fine mist spray is thereby reduced”) would be recognized by one of ordinary skill in the art as an inherent property of a salicylic acid spray with an increased pH, the declaration by Dr. Maibach, notwithstanding.

Accordingly, for the reasons described above, the 35 U.S.C. 103 rejections of claims 1, 2, 4, 5, 7-11, 13, and 15-20 are maintained.

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Applicant objects to Examiner's use of Fitzjarrell (US 5759559) arguing that Fitzjarrell "expressly states that salicylic acid acne treatments are 'often unsuccessful and may have significant side effects'." Applicant argues, therefore, that Fitzjarrell argues away from the limitations of claims 21 and 22. Examiner does not find Applicant's argument persuasive, however, because Fitzjarrell also states that "acne can be treated with diet changes, careful washing and nonprescription lotions containing benzoyl peroxide, topical creams containing *salicylic acid*, or other medications" and that "these treatments reduce the intensity or frequency of the face, the shoulders, neck, etc." (col. 1, lines 25-28 and 40-41) (emphasis added). Accordingly, despite the side effects of and varying degrees of effectiveness, it is Examiner's position that Fitzjarrell does in fact teach the use of salicylic acid for the treatment of acne. Furthermore, it is clear from the use of "**or**" in the recitation of possible acne treatments that, even though Fitzjarrell also teaches the combination treatment of a topical spray of niacinamide and an oral supplement, the "topical cream containing salicylic acid" taught in column 1, lines 27-28 can be utilized alone. Applicant also argues that the limitations: "adapted only for administration to non-facial body skin" and "whereby any nasal irritation or coughing caused by the fine mist spray is thereby reduced" are not addressed by Fitzjarrell. For the reasons described in the preceding paragraphs, these phrases are deemed to be recitations of intended use and inherent properties, respectively.

Accordingly, for all the reasons described above, the 35 U.S.C. 103 rejections of claims 21 and 22 are maintained.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

A handwritten signature in black ink, appearing to read 'Sreeni Padmanabhan', with a horizontal line underneath the name.

**SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER**